REMARKS

This application is amended in a manner to place it in condition for allowance at the time of the next Official Action.

Status of the Claims

Claim 29, 31, 37-40 and 44 are amended.

Claim 29 is amended to recite specific topical carriers. Support can be found in paragraphs [0030] through [0031].

Claim 31 is amended to clarify its meaning. Support can be found in [0010]. As explained in [0010], the invention comprises two embodiments:

- in the first one, the lipopeptide is administered topically to the subject in need thereof,
- in the second one, the peptide antigen used in the lipopeptide is administered by immunization to the subject prior the topical administration of the lipopeptide. For carrying out this second embodiment, one needs a combined product comprising 1) the lipopeptide and 2) the peptide antigen.

Claim 37 is amended to remove “preventing”.

Claims 38-40 are amended to specify that the peptide antigen capable of activating a Tr1 cell population.

Claim 44 is amended to recite specific carriers.

Claims 45 and 46 are new. These claims include the features previously recited in claims 38 and 40, respectively.

Non-elected and withdrawn claims 1-28, 33-36, 42 and 43 have been cancelled without prejudice, as Applicant reserves the right to file one or more divisional applications directed to their subject matter.

Claims 29-32, 37-41, remain in this application.

Claim Objections

Claims 29-32 and 37-41 were objected to for being improper dependent claims because they had ultimately depended from a method claim.

These claims are amended so as not to depend from a method claim, and withdrawal of the objection is respectfully requested.

Claim Rejections-35 USC §112, 2nd paragraph

Claims 31-32 were rejected under 35 U.S.C. §112, second paragraph, for being indefinite. This rejection is respectfully traversed for the reasons below.

Specifically, the "combined preparation" recitation had rendered the claims indefinite.

Claim 31 has been amended to clarify the meaning of the combined preparation, and, thus, claim 31 is now definite.

Therefore, withdrawal of the rejection is respectfully requested.

Claim Rejections-35 USC §112, 1st paragraph

Claims 37-40 and 44 were rejected under 35 U.S.C. §112, first paragraph, for not complying with the enablement requirement. This rejection is respectfully traversed for the reasons below.

The position of the Official Action was that the intended use of the pharmaceutical composition did not meet the enablement requirement, and, in particular, the prevention of a disease.

The term preventing is deleted from claim 37.

The present invention relates to the fact that a lipopeptide when administered topically to the subject in need thereof is capable of eliciting and activating a distinct T cell population depending on the peptide used.

In a first embodiment, when the peptide used is capable of eliciting and activating CD8+ T cells and/or CD4+ T cells, the lipopeptide administered topically is capable of priming a CD8+ and/or CD4+ T cell mediated immune response. This immune response thus allows the treatment of a skin disease or a disease of the mucosa such as melanoma.

This embodiment is supported by Example 2 showing that topical administration of TRP2 or OVA lipopeptide allowed the priming of a CD8+ and/or CD4+ T cell mediated immune response.

The person skilled in the art would be able to select the better peptide to elicit and activate CD8+ T cells and/or CD4+ T cells depending on the disease to treat, for example a tumor peptide for treating melanoma.

In a second embodiment, the peptide used is capable of eliciting and activating Tr1 cells, thereby allowing them to produce IL-10 in order to reduce inflammation.

This embodiment is supported in Example 1 showing that topical administration of OVA lipopeptide to BALB/c mice allowed the recruitment of Tr1 cells (CD25+ cells) specific of OVA near the site of administration. As BALB/c mice do not have naturally T cells specific of OVA, the injection of Tr1 cells specific of OVA was needed to demonstrate that the topical administration of this lipopeptide was able to prime the Tr1 cells and treat the inflammation. In the same way that the person skilled in the art would select a peptide capable of priming a CD8+ and/or CD4+ T cell mediated immune response, the person skilled in the art would be able to select a peptide capable of priming a Tr1 mediated immune response, for example a peptide not related to the inflammation to be treated and well-tolerated by the organism in order to avoid activation of pro-inflammatory T cells.

The Applicant thus considers that the person skilled in the art would know how to select the right peptide to prime the T cell population adapted for treating an inflammation of the skin or the mucosa or an infection or cancer of the skin or the mucosa.

Therefore, the claim 37-40 and 44 are believed to now comply with the enablement requirement, and withdrawal of the rejection is respectfully requested.

Claim Rejections-35 USC §102

Claims 29-32, 37-41 and 44 were rejected under 35 U.S.C. §102(a) as being anticipated by FOUSSAT et al., available on line November 7, 2003. This rejection is respectfully traversed for the reasons below.

The FOUSSAT et al. publication includes Foussat, Brun and Groux, who are the three inventors of the presently claimed subject matter.

Applicant submits herein duly executed Rule 132 Declarations (see the Appendix) stating that together the three inventors conceived and invented the subject matter disclosed in the FOUSSAT et al. publication that is being applied against the present claims.

Thus, this subject matter disclosed in the FOUSSAT et al. publication was not known or used by "others" prior to the claimed invention, and the publication does not qualify as prior art.

Therefore, withdrawal of the rejection is respectfully requested.

Claims 29-32, 37-41 and 44 were rejected under 35 U.S.C. §102(b) as being anticipated by LE GAL et al., 2003 (LE GAL). This rejection is respectfully traversed for the reasons below.

LE GAL teaches a composition comprising two peptides (MART 27-35 and TT 830-843) coupled to a palmitic acid in combination with IFA.

LE GAL does not teach a composition comprising a lipopeptide as described in independent claim 29, in combination with a pharmaceutically topical or cosmetically acceptable carrier is selected in the group consisting of emulsion carriers, anhydrous liquid solvents, oils, silicones, aqueous-based single phase liquid solvent.

Therefore, LE GAL fails to anticipate or render obvious the claimed invention, and withdrawal of the rejection is respectfully requested.

Conclusion

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following item:

- a 37 CFR 1.132 Declaration of inventors Groux, Brun and Foussat.